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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/581,583	06/02/2006	Allan Mishra	MISHRA.021NP	6996

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KNOBBE MARTENS OLSON & BEAR LLP
2040 MAIN STREET
FOURTEENTH FLOOR
IRVINE, CA 92614

EXAMINER
AFREMOVA, VERA

ART UNIT	PAPER NUMBER
1657	

NOTIFICATION DATE	DELIVERY MODE
12/08/2009	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

jcartee@kmob.com
eOAPilot@kmob.com

Office Action Summary	Application No.	Applicant(s)	
	10/581,583	MISHRA, ALLAN	
	Examiner	Art Unit	
	Vera Afremova	1657	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 September 2009 and 11 September 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *8,10 and 46-50* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) *8,10 and 46-50* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 8, 10 and 46-50 as amended (9/08/2009) are pending and under examination in the instant office action.

Claim Rejections - 35 USC § 112

Claims 8, 10 and 46-58 as amended are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 8 recites at least 2 composition including "a PRP composition" (intermediate product) and "a composition for dermatological application" (final product). Claim 8 as amended also recites that "the composition" is prepared without adding an exogenous activator. However, it is unclear as claimed which of 2 compositions (final or intermediate) does not contain "exogenous activator". The limitation drawn to the exclusion of "exogenous activator" is uncertain because "activator" as claimed is a generic ingredient and, thus, it is unclear as claimed what might be activated or not by this "activator".

Further, in claim 10, the limitation drawn to the exclusion of "exogenous activator" is particularly uncertain because collagen is "activator" for platelets. Thus, the importance of a non-activated PRP composition is compromised. The issue of activating effects provided by "cultured cells" is also uncertain as claimed and as disclosed.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 8 and 10 as amended are rejected under 35 U.S.C. 102(b) as being anticipated by US 2003/0175248 (Uhr, Gunter).

Claims are directed to a method of making a composition wherein the method comprises steps of extracting blood from a patient, concentrating platelets from the blood and combining the platelets with a skin permeation enhancer and a pharmaceutical carrier suitable for topical application to skin. Some claims are further drawn to the carrier being generic "cultured cells".

US 2003/0175248 (Uhr, Gunter) discloses a method of making a regenerative composition to be used in skin defects (entire document including abstract or 0013) or a composition suitable for dermatological applications. The cited method comprises step of extracting blood from a patient (0007), step of concentrating platelets from the blood for making platelets rich plasma or PRP (0008, 0009), step of adding/returning "particle-free plasma" (0010) or a generic "skin permeation enhancer" to PRP concentrate and step of combining the PRP composition with a pharmaceutical carrier such as calcium phosphate or calcium composite (0011). No thrombin or other platelet activating agent is added for making intermediate and/or final dermatological composition. With respect to the claim 10 it is noted that limitation drawn to incorporation of "cultured cells" as additional carrier is generic. Thus, the disclosure about using or recombining "cake" of platelets with other components is considered to anticipate claim 10 because platelets in "cake" remain or hold viable and, thus, they are "cultured cells" within the broadest meaning of the claims. Therefore, the cited document is considered to anticipate the presently claimed invention.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 8, 10 and 46-50 as amended are rejected under 35 U.S.C. 103(a) as being unpatentable over US 2003/0175248 (Uhr, Gunter), US 5,993,804 (Read et al) and US 5,733,571 (Sackler).

Claims are directed to a method of making a composition wherein the method comprises steps of extracting blood from a patient, concentrating platelets from the blood and combining the platelets with a skin permeation enhancer and a pharmaceutical carrier suitable for topical application to skin. Some claims are further drawn to the carrier being generic "cultured cells".

Some claims are further drawn to the carrier being a transdermal patch and/or to steps of combining the platelets-containing composition with components of the transdermal patch.

US 2003/0175248 (Uhr, Gunter) is relied upon as explained above for the disclosure of a method of making a regenerative composition to be used in skin defects (entire document including abstract or 0013) or a composition suitable for dermatological applications. The cited method comprises step of extracting blood from a patient (0007), step of concentrating platelets from the blood for making platelets rich plasma or PRP (0008, 0009), step of adding/returning "particle-free plasma" (0010) or a generic "skin permeation enhancer" to PRP concentrate and step of combining the PRP composition with a pharmaceutical carrier such as calcium phosphate or calcium composite (0011). No thrombin or other platelet activating agent is added for making

intermediate and/or final dermatological composition. With respect to the claim 10 it is noted that limitation drawn to incorporation of "cultured cells" as additional carrier is generic. Thus, the disclosure about using or recombining "cake" of platelets with other components is considered to anticipate claim 10 because platelets in "cake" remain or hold viable and, thus, they are "cultured cells" within the broadest meaning of the claims. The disclosed the platelets-containing compositions are intended for treatment of skin and they are made in a form of liquid or paste.

Thus, the cited US 2003/0175248 (Uhr, Gunter) is silent about incorporation of solid support adhesive materials or components of the transdermal patch into platelets-containing compositions.

However, US 5,993,804 teaches combining solid support materials including adhesives with platelets-containing compositions as intended for topical application and for healing skin wounds, for example: col. 11, lines 50-67 and col. 4, lines 21-40.

Furthermore, US 5,733,571 is relied upon to demonstrate that the use of transdermal patches is well known for delivery of medicinal agents and that the methods of preparing the transdermal patches include steps of combining components including permeable membrane (diffusion layer), impermeable membranes (backing and/or blocking layers) and adhesives with the active agent delivery matrix, for example: col. 5, lines 31-51.

Therefore, it would have been obvious to one having ordinary skill in the art at the time the claimed invention was made to modify the method of US 2003/0175248 (Uhr, Gunter) by adding steps of incorporating the RPR compositions into transdermal patches with a reasonable expectation of success in providing composition suitable for skin application because with

platelets-containing compositions are combined with support materials for topical applications and the use of transdermal patches is well known in the art for delivery of various medicinal agents. Thus, the claimed invention as a whole was clearly *prima facie* obvious, especially in the absence of evidence to the contrary.

The claimed subject matter fails to patentably distinguish over the state art as represented be the cited references. Therefore, the claims are properly rejected under 35 USC § 103.

Response to Arguments

Applicant's arguments filed 9/08/2009 and the contents of Declaration by Allan Misha have been fully considered but they are not all found persuasive.

Claim rejection under 35 U.S.C. 102(b) as being anticipated by US 5,599,558 (Gordinier et al) and being unpatentable over US 5,599,558 (Gordinier et al) have been withdrawn because the PRP plasma is activated with thrombin in the method of for making a pharmaceutical composition suitable for topical dermatological applications as disclosed by US 5,599,558 (Gordinier et al).

Applicant's arguments with respect to claim rejected under 35 USC § 103 have been considered but are moot in view of the new ground(s) of rejection.

The contents of Declaration and arguments based thereon have been fully considered however they are not persuasive because the results of the declaration are confusing as to the significance of the differences between non-activated and activated PRP. Moreover, the contents of declaration are mostly related to a method of cell co-culturing rather than to the claimed

product. The scope of the showing must be commensurate with the scope of claims to consider evidence probative of unexpected results.

With regard to the cited US 5,993,804 applicant argues that it teaches lyophilized platelets not PRP. However, US 5,993,804 was/is relied upon for teaching about combining solid support materials including adhesives with platelets-containing compositions as intended for topical application and for skin healing. Moreover, US 5,993,804 also teaches incorporation of some generic skin permeation enhancers such as buffered saline, trehalose, albumin into topical composition with "unactivated" or "non-activated" platelets.

The cited US 5,733,571 clearly teaches a transdermal patch including permeable membrane and impermeable membranes as intended for delivery of dermatologically active drug. Thus, it is a prior art relevant to the instant application and claims.

No claims are allowed.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Vera Afremova whose telephone number is (571) 272-0914. The examiner can normally be reached from Monday to Friday from 9.30 am to 6.00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Manjunaht Rao, can be reached at (571) 272-0939.

The fax phone number for the TC 1600 where this application or proceeding is assigned is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Technology center 1600, telephone number is (571) 272-1600.

Vera Afremova

December 3, 2009

/Vera Afremova/

Primary Examiner, Art Unit 1657